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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,765	04/20/2004	James Fink	016770-007100US	5232

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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,765	FINK ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/07 has been entered.

Status of Claims

Claims 1-19 have been cancelled, and claims 20-28 are pending in the instant application.

Response to Arguments

Applicant's arguments filed on 2/9/07 have been fully considered but they are not persuasive for the following reasons.

First, Applicant contend that neither Downs nor Berggren et al, along or in combination, teach or suggest the claimed method of respiratory therapy comprising the steps of providing a lower volume flow of gas in a pressure assisted breathing system and introducing aerosolized medicament into that lower volume flow of gas as cited in the amended claims 20 and 23 (see arguments filed on 2/9/07, page 5, lines 7-12), however, these arguments are not well taken because Downs discloses a system where a positive airway pressure is maintained across conduits 14 and 16, however, upon inhalation a negative pressure is introduced in conduit 16, thus inherently creates a lower flow volume at the negative pressure detection point while maintains a higher flow at the outlet of a pressure generator (see cols. 4 and 5 of Downs). Since Downs lacks the method steps of "introducing an aerosolized medicament into the lower volume

flow of gas in the respiratory circuit" of claim 20, however, combined teachings of Downs and Berggren render the method step obvious. Berggren teaches a CPAP system (fig.) comprising a nebulizer coupled to the respiratory circuit for the purpose of providing surfactant to newborns suffering from respiratory distress syndrome in order to improve alveolar gas exchange and thereby improve their chance of survival (page 460, col.1, lines 1-3). Therefore, it would have been obvious to modify the CPAP system of Downs to couple a newborns suffering from respiratory distress syndrome in order to improve alveolar gas exchange and thereby improve their chance of survival as taught by Berggren. Furthermore, it would have been obvious to one of ordinary skill in the art to inherently obtain the method step of introducing aerosolized medicament into that "lower gas flow volume" because as established in the precedent statements, upon inhalation the gas flow near the interface would be lower, thus medicament traveling with the flow would be introduced at the lower volume prior to inhalation.

Second, Applicant argues that "Downs teaches away from two different gas flows by describing conduit branch 16 as merely an extension of conduit 14 in the delivery of gas to the patient...one skilled in the art would not expect the gas flow to be any different in conduits 14 and 16" (see arguments filed on 2/9/07, page 5, lines 17-23). Examiner takes the position that in a conventional positive pressure ventilation system a transient increase in pressure is maintained in a conduit/gas line provided between a generator and a patient interface in order to keep the airway open, such concept is reiterated in Downs (see col.4 lines 64-68). While the Examiner is in agreement that differences in gas flow is not observed between conduits 14 and 16, conversely, takes the position that Applicant's invention as well could not possibly have a differential pressure between lines 8 and 13, unless a negative pressure is created across lines 8

and 13, hence leading to a lower flow at the negative pressure detection site. According to Applicant's disclosure, that negative pressure is created during inspiration, which is taught by Downs (see col.5 lines 4-6). Thus, Downs teaches differences in gas flow in conduits 14 and 16 as possible.

Last, Applicant further argument with respect to "Berggren et al does not teach or suggest, either in Fig.1 or in the accompanying discussion, providing a respiratory circuit with a lower volume gas flow and introducing the aerosol in the gas flow. As pointed out in Applicants' previously response, it is clear that Berggren et al fail to recognize the benefit of introducing the aerosol into a lower volume flow of gas to minimize the loss of aerosol in the CPAP system." (see arguments filed on 2/9/07, page 5, lines 24-30) is not well taken. As established in the precedent paragraph, Berggren reference was introduced to teach an aerosolized medicament can be introduced in a respiratory therapy. Thus, the combined teachings of Downs and Berggren render "providing a respiratory circuit with a lower volume gas flow" of the claimed invention obvious.

For the above stated reasoning, Examiner considers references to Downs and Berggren can be applied to reject amended claims 20 and 24.

Specification

Claims 20 and 24 are objected to because of the following informalities: in claim 20, line 8, recitation of "introducing an aerosolized medicament into the lower volume flow of gas", and in claim 24, line 10 recitation of "entraining the aerosolized surfactant into the second low volume gas flow", specification does not provide adequate support for the cited recitations. Examiner acknowledges that Applicant cited that "nebulizer 6 emits an aerosolized medicament

9 into gas flow 8" (see page 5, lines 12 and 13), and such statement shows surfactant is introduced at high volume gas flow (flow 8), not at the low volume gas flow as required by the claimed invention. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,2,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downs US 4,773,411 in view of Berggren et al. (Acta Paediatr 89: 460-4, 2000).

As to claim 20, Downs discloses a method of respiratory therapy comprising the steps of providing a pressure-assisted breathing system having a pressure-generating circuit (12,14) and a respiratory circuit (16) adapted to be coupled to a patient interface device (20 and col.3, lines 57-64). With respect to "providing the respiratory circuit with a lower volume flow of gas than the pressure generating circuit", Downs teaches a negative flow upon inhalation at the interface, thus providing flow at the interface (respiratory circuit) somewhat lower than flow at the outlet of the generating circuit (see col.3, lines 57-54, and col.5 lines 4-14). Downs further discloses the step of coupling the patient interface device to the patient's respiratory system (col.3, lines 57-64). Downs however lacks introducing an aerosolized medicament into the lower volume flow of gas in the respiratory circuit to deliver the medicament to the patient's respiratory system. However, Berggren in a CPAP system (fig.1), teach a nebulizer coupled to the respiratory circuit for the purpose of providing surfactant to newborns suffering from respiratory distress syndrome in order to improve alveolar gas exchange and thereby improve their chance of survival (page 460, col.1, lines 1-3). Therefore, it would have been obvious to modify the CPAP system of Downs to couple a nebulizer to the respiratory circuit because it would have provided surfactant to newborns suffering from respiratory distress syndrome in order to improve alveolar gas exchange and thereby improve their chance of survival as taught by Berggren.

Claims 21-23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downs 4,773,411 in view of Berggren (Acta Pediatric 89: 460-4, 2000) as applied to claims 20 and 24 above, and further in view of Davison GB 2,272,389.

As to claim 21, Downs as modified by Berggren lack a vibrating aperture-type aerosol generator for aerosolizing the liquid medicament and a connector for connecting the nebulizer to the respiratory circuit so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. However, Davison teaches a vibrating aperture-type aerosol generator (fig.2) for aerosolizing the liquid medicament and a connector (2) for connecting the nebulizer to the respiratory circuit (32) so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. An advantage of the vibrating aperture-type aerosol generator is that it facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose (page 2, lines 10-13).

As to claim 22, Davison teaches the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13).

As to claim 23, Davison discloses a reservoir (14) having a variable capacity (fig.2); consequently, it would have been obvious to adjust the volume of the reservoir to any desired volume including 4ml or less.

As to claim 24, Downs as modified by Berggren as further modified by Davison as discussed above with respect to claim 20 and 21 also teach a method of delivering surfactant medicament to a patient's respiratory system (Berggren) and entraining the aerosolized surfactant into the respiratory circuit, whereby the patient breathes the aerosolized surfactant through the patient interface device (fig.2 of Davison).

As to claim 25, Berggren discloses the surfactant is phospholipids (page 461, col.1, lines 4-5).

As to claims 26 and 28, Downs lacks wherein 6-18% of the aerosolized surfactant is delivered to the patient and wherein the dose is equal to 10 mg or less of surfactant. However, the particular amount of each dose and the particular amount of aerosolized medicament that is delivered to a patient in Berggren as further modified by Davison can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular amount including 6-18% and 10mg or less. Berggren disclose diluting surfactant prior to mobilization (page 461, col.1) and Davison teaches a variable capacity reservoir (14) which controls the dose size; consequently, the particular amount and concentration of medicament is dependent upon the particular medical needs of a patient and is adjusted accordingly.

As to claim 27, Davison teaches the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hoenig (US 4,323,064), Christian (US 4,502,481), and Bird (US 4,127,123) are cited to teach administration of aerosolized medicament through a positive airway system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Shumaya B. Ali. 3/1/2007
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3/5/07